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OCTOBER 2014

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From Outsourcing To Partnersourcing: Pfizer Puts CMOs To The Test

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If you have a molecule in production and are ready to outsource it, how do you know which CMO will be best qualified to handle it? How can you definitively know the strengths and weaknesses of a handful of CMOs under consideration? And more importantly, how can you tell which CMO will most closely align with your own organization's culture and principles?

Site visits, audits, and RFPs will provide you with some of the information you require (cost, for example), but may still not tell you everything you need to know. Is one CMO better than another when it comes to large versus small batches? What about quality and timeliness? What is their track record when it comes to reliability? Unfortunately, if a sponsor has different teams performing the reviews, that could also inject variability into the process.

When Pfizer decided to move from a functional outsourcing model to a partnering model, company executives realized they needed a way to evaluate the culture and capabilities of a list of CMOs. To accomplish this, Pfizer undertook a multimillion dollar exercise that included sending one monoclonal antibody project to different vendors. The case study was co-presented by Pfizer and Cook Pharmica in a session titled *Moving from Outsourcing to Partnersourcing* at the

2014 Biopharmaceutical Development & Production conference in San Diego.

ALIGN YOUR PRIORITIES AND PRINCIPLES

At Pfizer, there are six guiding principles that have been adopted internally to guide the everyday behavior of all company employees. In selecting the CMOs to participate in the study, Pfizer set out to identify firms exhibiting these same principles. Pfizer keeps these principles in mind when evaluating a CMO, and



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each one carries a different rating.

“The first principle, which is always at the top of our list, is quality,” says Dr. Sonia Kansal, senior manager of biotherapeutics and vaccines outsourcing at Pfizer. “If quality is the key component for everything that we do, we obviously attempted to make sure the CMOs we selected had a solid history of quality. In evaluating this tenet, it helped if the CMO had been inspected by the FDA and had a positive regulatory outcome. However, we did not make that a requirement. This is an area where we had to give companies a little leeway. Regulatory inspections can be an issue for some firms, since they may want to get audited but can’t because they don’t manufacture a commercial product.”

Confidentiality is the second principle, and Pfizer prefers to work with CMOs that view it with equal importance. Discussing the company’s projects with another client would be considered a severe breach of trust. Kansal notes the possibility of leaked information is a risk companies take on every time they outsource a project. While it’s difficult to measure how confidential a CMO might be, there are ways of determining how willing a potential partner might be to share information. “If we visit a CMO and they start discussing an early-phase product they are manufacturing for another client, that would send up an immediate red flag,” she says. “Having a regulatory strategy in place is also a plus for us.”

Spending the company’s money in a cost-effective manner is another important principle, although Kansal is quick to note that in the pre-commercial space, this factor is not as critical as the others. The company simply wants to make sure it is being charged a fair price for the work performed. Pfizer will often request a quote from several companies and receive figures that are two or three times higher than what other companies are asking. For that reason alone it always needs to be a consideration when choosing a CMO.

Perhaps the only principle that rivals quality in terms of importance is timeliness. The old adage “time is money” holds true in pharma, so minimizing the time to proof of concept as much as possible is

critical. This will also lead to Pfizer being able to maximize the number of proof of concepts being completed per year.

Flexibility and adaptability are the two final factors to look for, and Kansal tends to group the two together. She notes many things can change after the start of a project with a CMO, especially planned timelines. She views flexibility as the ability of the CMO to respond to scheduling changes imposed by the sponsor, as well as having the resources and technology platforms in place to meet Pfizer’s needs. Adaptability is the CMO’s ability to meet shifting environment and project needs.

“There is one additional principle that is also important to us, and that is location,” she says. “We would prefer to not work with too many CMOs that are located where it would take us a full day (or more) to get there. We also tend to shy away from a CMO that had five different locations, for example, that we need to work with. Even if each location has the same quality system in place, a different culture often exists in each location, which can make for a more difficult partnership. We have all heard stories of companies with a top-notch quality system that will get an FDA warning letter for a subsidiary in a different location.”

WHICH MODEL IS MOST APPROPRIATE?

When outsourcing to CMOs, Kansal believes there are two basic models, each with its own pros and cons. There is the functional model where various functions are outsourced to companies with a specialty in certain areas, such as analytical, drug substance, or drug product. When using this approach Pfizer seeks CMOs with a good history of working with a specific drug substance. With this type of relationship, sponsors are able to take advantage of the specialization that each CMO can bring to the table. “You can get quotes from 10 different vendors and see if one of them is offering a lower price, better or additional services, or more timely delivery. There is also a good amount of flexibility there to leverage the relationship in ways that will most benefit the sponsor.”

The biggest negative to this type of relationship is it can create a longer and more complex supply chain. If using three dif-

ferent CMOs, a sponsor will have to manage three different vendors, have three times the travel time, three times the qualification effort, etc. This also will add time to the entire life cycle and delay the important proof of concept.

Alternatively, when utilizing a single vendor location, that vendor will provide all necessary services. In this case the pros are a strategic partnership where a company is working with just one quality system, one executive leadership team, and one set of project managers. “This model allows a firm to gain cost and time efficiencies, which will get product to clinics much faster. “The downside for the company is placing a lot of risk in the hands of a single provider,” warns Kansal.

The study performed by Pfizer was intended to determine whether this type of strategic partnership could actually work. All the vendors selected were not single-location companies, and in some cases, there were different companies within the same location.

To make sure Pfizer was always comparing apples to apples, key project attributes were put in place. First, each CMO under evaluation had to have a global presence. To minimize variability in the evaluation process, the same technical team was used to evaluate all of the vendors, albeit with different project managers. Extensive milestone tracking systems were used internally to keep a close eye on what was occurring. Kansal notes not all of the tracking information was shared with each vendor.

“We also made sure we were able to have a separate budget set up for each CMO participating in this experiment,” says Kansal. “We wanted to determine the true cost of outsourcing for each of the CMOs involved. You can only do that if there is a way to keep the budgets completely separate.” Kansal notes travel costs were also included, since they can add up quickly if a vendor is located 6,000 miles away.

IMPORTANT LESSONS LEARNED

There were numerous lessons Pfizer learned from conducting this exercise in CMO “speed dating.” The company wanted to ensure subject-matter experts were

engaged with each other from the very start. This involved literally taking a bus load of experts to the CMO site for the initial technical evaluation. "This was an incredibly critical step," says Kansal. "We had our subject-matter experts talking to each other, forming close relationships from the very beginning. That led to better partnering and communication throughout the entire project. When it came time to form sub teams, the team members already knew each other and were able to immediately start discussing the project specifics."

Also closely related to the communications effort were numerous meetings with each CMO to keep everything on track. Meetings were held weekly, but even more often when necessary. Kansal says Pfizer personnel traveled to the CMO locations as much as possible, noting in these partnering relationships that nothing beats the value gained from face-to-face meetings.

Perhaps one of the biggest lessons learned was the importance of trust in partnersourcing. Kansal believes this is one facet of the relationship that cannot be compromised. "You don't meet people and immediately trust them," she says. "True trust can only be built over time, and this effort enabled us to work with all five companies for an extended period."

A final lesson learned was the importance of project responsibility. While ultimate responsibility for a project lies with the sponsor, Kansal noticed some CMOs seemed to take a lot of pride in co-owning the project. "They didn't have to, but we saw it as making the effort to go above and beyond," she says. "Some simply saw it as

their own project. That is always nice for the sponsor. We saw that as a sure-fire way for a CMO to build our trust, and that is also how you build a strategic partnership that will help in all future relationships."

Pfizer certainly gained a lot of vendor

insight as well. Each CMO had expertise in different areas. Some were stronger upstream and others downstream. In the future, when faced with an actual project, the company will know where to turn for needed capabilities. 

Collaborative Approach Helps CMO Meet Project Goals

When delivery dates are a concern, developing a process from scratch can be tricky, since timelines can add pressure to make quick decisions that may not serve the best long-term interests of the project. For this exercise, Cook Pharmica was asked to develop a process and platform approach that would yield the best end result: a well-defined process that could be used to support a broad pipeline of projects. "Generally, when a large pharmaceutical company comes to you with a proposal, they will dictate the terms of the project and how to develop the process," says Frank Marchesani, business development executive at Cook and a co-presenter (along with Pfizer) of the *Moving from Outsourcing to Partnersourcing* session at the 2014 Biopharmaceutical Development & Production conference. "In this case, we were able to develop the process from the ground up, presenting us with the chance to impress the client with our capabilities."

Unlike the standard practice of outsourcing a molecule, where there is a strict emphasis on keeping costs down and timelines tight, the partnersourcing model enabled a more collective effort between Pfizer and Cook. "For us, the partnering model is consistent with the collaborative culture and approach we take with all our clients and their projects," adds Marchesani. The development of close working relationships between subject-matter experts from both organizations, ensuring better understanding and alignment, was just one of several benefits of the model. As the project progressed, it became clear that not only was there a good cultural fit between the two teams, but the collaborative nature of the project enabled Pfizer to leverage some of the development expertise at Cook Pharmica to improve the process.

Ultimately, Cook was able to deliver on the challenge and provide a quality product that met all the project requirements. Equally important, both parties learned from each other, developing a relationship of trust to apply to future opportunities, and proving that the partnersourcing approach works.



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